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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTICALS LLC, TAKEDA PHARMACEUTICALS AMERICA, INC., and ETHYPHARM, S.A.,	:	Civil Action No. 3:10-CV-01723-JAP-TJB
Plaintiffs and Counterclaim-Defendants,	:	
v.	:	
ZYDUS PHARMACEUTICALS (USA) INC. and CADILA HEALTHCARE LIMITED,	:	MEMORANDUM IN SUPPORT OF TAKEDA'S MOTION FOR SPOILIATION SANCTIONS IN THE FORM OF EXCLUSION OF ZYDUS' EVIDENCE OF PARTICLE SIZE TESTING ON PRE-TABLETED GRANULES
Defendants and Counterclaim-Plaintiffs.	:	CONFIDENTIAL – TO BE FILED UNDER SEAL

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The Takeda Plaintiffs¹ ("Takeda") submit this memorandum in support of their motion for spoliation sanctions against Defendants Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Limited (together, "Zydus").

PRELIMINARY STATEMENT

This is a patent infringement action under the Hatch-Waxman Act in relation to Prevacid[®] SoluTab[™], Takeda's orally disintegrating tablet ("ODT") formulation of its blockbuster drug Prevacid[®]. The three Takeda patents-in-suit² require the claimed ODT to include, among other things, enteric coated granules of specified particle sizes ("particle size requirements"). [REDACTED]

¹ The Takeda Plaintiffs are Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals North America, Inc., Takeda Pharmaceuticals LLC, and Takeda Pharmaceuticals America, Inc.

² U.S. Patent Nos. 6,328,994 (the "'994 patent"), 7,431,942 (the "'942 patent"), 7,875,292 (the "'292 patent").

[REDACTED] (See Ex. 1, 2/17/12 e-mail from S. Moore to A. Chow). [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Zydus' gamesmanship should not be countenanced by the Court. Zydus should not be permitted to benefit from evidence in its sole possession, custody and control that it destroyed or has made otherwise unavailable. [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]

STATEMENT OF FACTS

A. The Takeda Patents-in-Suit Incorporate a Particle Size Requirement for Granules

The Takeda patents-in-suit are directed toward a novel orally disintegrating tablet formulation containing fine lansoprazole microgranules. Upon disintegration of the tablet, these small granules remain in the mouth so that they can be easily swallowed. Specifically, the '994 patent claims "fine granules" that have "an average particle diameter of 400 μm or less." This Court construed this term to mean "fine granules up to and including the enteric coating layer having an average particle diameter of 400 μm ($\pm 10\%$) or less." (D.I. 113). The '942 and '292 patent claims are similar to that of the '994 patent, except that the "fine granules" include a mannitol coating layer on top of the enteric coated granule. Further, the '942 and '292 patents require that the "average particle diameter" of the "fine granules" be "300 to 400 μm " and "400 μm or less," respectively. Based on the same considerations as the '994 patent, this Court construed the '942 patent as also incorporating a measurement variation of $\pm 10\%$ (D.I. 113); the parties stipulated that claim construction of the '994 and '942 patents would control claim construction of the '292 patent. (D.I. 97).

B.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (See Ex. 2, Paragraph IV Notice Letter at pp. 61-63, 73-74). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] *Id.*

[REDACTED]

[REDACTED] (Ex. 3). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

C. [REDACTED]

On August 10, 2010, Plaintiffs propounded production requests, seeking to obtain, among other things, samples of Zydus' pre-tableted granules. (Ex. 4, Plaintiffs' First Production Requests). Zydus represented that it would "produce samples, if any, responsive to the request." (Ex. 5, Defendants' Responses to Plaintiffs' First Production Requests). [REDACTED]

[REDACTED] (Ex. 6, 12/15/10 e-mail from A. Chow to J. Moriarty). [REDACTED]

[REDACTED] (Ex. 7, 12/17/10 e-mail from J. Moriarty to A. Chow). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (Ex. 8, 3/23/11 e-mail from J. Moriarty to D. Kim).

[REDACTED]
[REDACTED]

[REDACTED] (Ex. 9, Plaintiffs' Second Interrogatory). [REDACTED]

[REDACTED]
[REDACTED]

• [REDACTED]
[REDACTED]
[REDACTED]

• [REDACTED]
[REDACTED]

• [REDACTED]
[REDACTED]
[REDACTED]

• [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

(Ex. 10, Defendants' Response to Plaintiffs' Second Interrogatory) [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

D. [REDACTED]

The parties exchanged opening expert reports on January 17, 2012. [REDACTED]

[REDACTED]

[REDACTED] (Ex. 11, Meyer-Stout Report [REDACTED])

[REDACTED] *see also* [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (Ex. 11, Meyer-Stout Report [REDACTED])

[REDACTED]

[REDACTED] *see also* [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]³

³

[REDACTED]

E.

(Ex. 1, 2/17/12 e-mail from S. Moore to A. Chow).

Id.

Id.

ARGUMENT

A.

"Spoliation is 'the destruction or significant alteration of evidence, or the failure to preserve property for another's use as evidence in pending or reasonably foreseeable litigation.'" *Mosaid Techs. Inc. v. Samsung Elecs. Co., Ltd.*, 348 F. Supp. 2d 332, 335 (D.N.J. 2004) (citation omitted). The duty to preserve relevant litigation evidence 'arises when the party in possession of the evidence knows that litigation by the party seeking the evidence is pending or probable and the party in possession of the evidence can foresee the harm or prejudice that would be caused to the party seeking the evidence if the evidence were to be discarded.' *Katiroll Co., Inc. v. Kati Roll and Platters, Inc.*, Civil Action No. 10-3620 (GEB), 2011 WL 3583408, *1 (D.N.J. Aug. 3, 2011) (citation omitted).

[illegible]

B.

"Spoliation sanctions serve a remedial function by leveling the playing field or restoring the prejudiced party to the position it would have been without spoliation. They also serve a punitive function, by punishing the spoliator for its actions, and a deterrent function, by sending a clear message to other potential litigants that this type of behavior will not be tolerated and will be dealt with appropriately if need be." *Mosaid*, 348 F. Supp. 2d at 335. Spoliation sanctions include: dismissal of a claim or granting judgment in favor of a prejudiced party; suppression of evidence; an adverse inference (*i.e.*, the spoliation inference); fines; and attorney's fees and costs. *Mosaid*, 348 F. Supp. 2d at 335.

In determining whether sanctions such as exclusion of evidence are warranted, the Court considers: '(1) the degree of fault of the party who altered or destroyed the evidence; (2) the degree of prejudice suffered by the opposing party; and (3) whether there is a lesser sanction that will avoid substantial unfairness to the opposing party and, where the offending party is seriously at fault, will serve to deter such conduct by others in the future.' *Id.* (citation omitted).

Compared to dismissal, this Court has described the sanction of excluding evidence to be "[a] lesser sanction, but an effective one because it can put the parties on a level playing field and deter future discovery violations." *Quaglietta v. Nissan Motor Co., Ltd.*, No. Civ. A. 97-5965, 2000 WL 1306791, *2 (D.N.J. Aug. 16, 2000), *aff'd*, 281 F.3d 223 (3d Cir. 2002).

Exclusion of evidence is warranted here.

[illegible][illegible]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] This Court has excluded evidence under similar circumstances where a party failed to preserve critical evidence, thereby prejudicing the opposing party's ability to present a defense. *See, e.g., Quaglietta*, 2000 WL 1306731 at *3 (in a case involving claim against car manufacturer for injuries suffered from alleged negligent manufacture of a truck, the court found that plaintiff spoliated evidence where plaintiff discarded the truck and "took away all possibility for defendant to inspect the truck and prepare a proper defense" and found "that the proper sanction is to exclude plaintiff's evidence regarding the condition of the truck, which includes the photographs and any evidence based on them.") [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

CONCLUSION

For the foregoing reasons, Takeda respectfully requests that this Court exclude Zydus' evidence of particle size testing of pre-tableted granules. [REDACTED]

[REDACTED]

[REDACTED]

Dated: February 21, 2012

Respectfully submitted,

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